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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,519	02/28/2002	Jean-Christophe Audonnet	454313-2250.1	1340

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 10/085,519	Applicant(s) AUDONNET ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-18* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Claims 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10, and in the interview of April 8, 2003 (described in the Interview Summary, Paper 11).

2. Applicant's election with traverse of Group I, and subgroup wherein the plasmids encode the bovine parainfluenza virus 3 (BPIV-3) hemagglutinin/neuraminidase (HN) and fusion (F) proteins in Paper No. 10, and in the interview of April 8, 2003 (described in the Interview Summary, Paper 11), is acknowledged. The traversal is on the ground(s) that there is no undue burden in examining the inventions together. In performing the search, the Examiner has found the Applicant to be correct with respect to the compositions comprising the compositions of plasmids encoding the HN protein, the F protein, or both proteins. The restriction requirement is therefore withdrawn as to claims to these compositions. However, the Examiner is not persuaded by the traversal with regards to the method claims, which, as demonstrated by claim 16, may require more than simply the administration of the claimed composition. The search for this method is not coextensive with the search for the claimed composition. The restriction is therefore maintained as to the methods of Group II

It is noted that under the practice required by In re Ochiai, as described in the Restriction requirement, claims to methods of using compositions in an allowed product claim will be

rejoined with the allowed product provided the method claims include the limitations of the allowed product.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on February 28, 2002, and February 13, 2003, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Specification

4. Receipt of the substitute specification is noted, and the written description of the substitute specification has been entered.

Claim Objections

5. Claim 12 is objected to because of the following informalities: the claim refers to the bovine parainfluenza virus type 3 (BPIV-3) hemagglutinin/neuraminidase and fusion proteins by their respective letter abbreviations (HN and F) without first identifying the proteins by their full names. Appropriate correction is required.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 12-15, and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 84-91, 93-95, 141-143, 149, and 150 of copending Application No. 09/760,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the two applications are overlapping. The claims of the present application read on an immunogenic composition comprising at least one plasmid encoding the HN and (or) the F proteins of BPIV-3. The copending application reads on vaccines comprising such plasmids (see e.g. claims 141-143, and specification pages 16-17), along with other compounds. Although the specification of the copending application teaches that the vaccine may comprise DNA encoding one or both of the "optimized" BPIV-3 HN and F antigens, because the claims also read on DNA encoding non-optimized antigens, it would have been obvious to those in the art that the non-optimized antigens could also be combined in the same DNA vaccine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The above rejection is, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention, which are not elements in the claim itself.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 12-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klippmark et al., J Gen Virol, 71:1577-80, in view of Suzu et al., Nuc Acids Res 15(7): 2945-58

(Genebank Accession Y00115), and further in view of the combined teachings of Felgner et al., WO 90/11092, and Crowe et al., Vaccine, 13(4): 415-21 (of record in the IDS filed on February 28, 2002). In this rejection, the above references are also considered in light of the teachings of Wathen et al., U.S. 5,169,628; and Babuik et al., Annals of the NY Academy of Sciences 772:47-63 (also of record in the February 28, 2002 IDS). The rejected claims read on immunogenic compositions against BPIV-3 comprising one or more plasmids encoding one or both of the HN and F proteins of the virus, and to methods of inducing immunological responses using the compositions.

The Klippmark reference teaches that the BPIV-3 HN and F proteins are immunogenic against infection by the virus, and that vaccines comprising these subunits are known to confer protection against the virus in animals. However, the reference does not teach the making of an immunogenic composition comprising plasmids capable of expressing the proteins in a vertebrate. Suzu teaches the DNA and RNA sequences coding for these proteins.

Felgner teaches methods of expressing exogenous DNA in animals such that exogenous polynucleotides are expressed. Abstract. Among the uses taught for such a method is for the immunization of an animal against a virus from which the polynucleotide was derived. Pages, 13, and 14-15. Felgner also teaches that genes for multiple proteins may be placed into a single plasmid. Pages 18-19. In addition to the teachings of Felgner, the Crowe reference further teaches that plasmid DNA vaccines have several advantages over the administration of virus particle or polypeptide vaccines. Pages 418-19. The reference suggests that the new vaccine technology would be useful in the immunization against PIV-3. In view of these teachings, suggesting the utility of DNA vaccines, one of ordinary skill in the art would have been

motivated to combine the teachings of these references with those of Klippmark and Suzu to make such a vaccine for BPIV-3.

From the teachings of Klippmark, Suzu, and Felgner, those of ordinary skill in the art would have known how to have construct DNA plasmids encoding one or both of the HN and F BPIV-3 proteins such that the plasmids could be administrated in a DNA vaccine. It is submitted that those of ordinary skill in the art would have been able to perform the appropriate genetic manipulations. See e.g., Wathen, column 1, lines 41-59 (stating that the HN and F proteins have been recombinantly expressed in viral vectors, and thereby evidencing that one of ordinary skill in the art would know how to make a plasmid encoding the proteins, as making plasmids are less complex, and often involved in, the making of recombinant viruses). One of ordinary skill in the art would also have had a reasonable expectation that such a vaccine would be effective in cows as Felgner teaches that the method may be used to immunize vertebrates generally, and a like vaccine against a different virus was successful in bovines. See, Babuik, page 53 (demonstrating that a DNA plasmid vaccine against bovine herpes virus 1 was effective). Thus, the identified references render the claimed compositions and methods obvious.

Conclusion

11. No claims are allowed.

12. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant it is not used as a basis for rejection for the stated reasons.

Ray et al., J. Virol 62(3): 783-87, this reference is considered redundant to Klippmark.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
May 20, 2003

James C. Housel 6/1/03

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